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Remarks

Claims 1 through 5, 9 and 10 remain pending in the application. Applicant has amended the claims to specify the amount of heat the heating elements can produce and to address antecedent basis issues. Applicant has added claims 11 through 22 as dependent claims. Claims 11 through 13 specify that the heating element is a resistive heating element. Claims 14 through 16 specify that the vacuum source is capable of producing a vacuum sufficient to draw the tissue near the valve or sphincter in contact with the heating element. Claims 17 through 22 include limitations to the power source, requiring it to be operable to provide sufficient energy to the heating elements to thermally damage the tissue near the valve. The cited reference does not show or render obvious the limitations of these claims.

The Office Action rejects claims 1 through 5, 9 and 10 as anticipated by Ramsey, III, Esophageal Catheters and Method of Use, U.S. Patent 6,148,222 (Nov. 14, 2000) under the assertion that Ramsey discloses a device having a catheter body, a plurality of balloons located at the distal end of the catheter and a plurality of heating elements and wires; and that a vacuum source operably connected to the suction lumen is inherently disclosed since Ramsey discloses that the ports may function as what the Office Action characterizes as aspiration ports. In the response to argument section, the Office Action states that Applicant appears to be arguing intended use, that all of the limitations are explicitly disclosed or inherently present and that an argument directed to intended use is irrelevant. The Office Action also asserts that because the electrodes produce heat when an electrical current is generated, the electrodes are heating elements.

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Regarding the intended use issued raised by the Office Action, the Examiner has misapprehended Applicant's argument with respect to Ramsey. Applicant is pointing out that the claims are structurally different from the devices shown in Ramsey. Arguments that mention the use of the claimed device help establish the lack of a motivation to alter the Ramsey device, meaning that the claims are also non-obvious over Ramsey.

The Office Action asserts that Ramsey inherently shows a vacuum source connected to what the Office Action characterizes as aspiration ports. Ramsey does not refer to the ports in this way; rather, Ramsey calls these objects "ports," "electrolyte ports," "access ports," or "fluid ports" and thus gives no indication as to how the fluid is removed through the port. The term "aspiration port" originates with the Examiner, and not with the reference.

With regard to the doctrine of inherency, the United States Court of Appeals for the Federal Circuit has stated that:

If an element is not expressly disclosed in a prior art reference, the reference will still be deemed to anticipate a subsequent claim if the missing element is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.

*Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art.*

Rosco Inc. v. Motor Lite Co., 304 F.3d 1373, 1380 (Fed. Cir. 2002). (Emphasis added, additional citations omitted.)

Ramsey does not necessarily show a vacuum source. The fluid used in the Ramsey system may be removed through the ports in several ways, including siphoning (by connecting the proximal end of the lumen to a point lower than the port), draining (by

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physically tilting the patient until the fluid drains through the port), or pumping. Since alternative ways of eliminating fluid from the space between the balloons are available, a vacuum source is not necessarily present in Ramsey. Thus, a vacuum source is not inherently disclosed in Ramsey and accordingly Ramsey does not anticipate any of the claims.

With respect to newly added claims 14 through 16, Ramsey neither explicitly nor inherently shows a vacuum source capable of creating a vacuum sufficient to draw the tissue near the valve or sphincter in contact with the heating elements. Thus, claims 14 through 16 are also novel and non-obvious.

With regard to the Office Action assertions that the Ramsey electrodes are heating elements, Applicant has amended the claims to recite that the heating elements are capable of producing heat sufficient to shrink the tissue near the valve. Ramsey does not explicitly show this structural limitation. Ramsey does not inherently show this limitation, or render it obvious, since Ramsey specifically avoids heating the esophagus. In other words, even if the Ramsey electrodes produce heat, the heat produced is certainly not enough to shrink the tissue of the esophagus.

Regarding claims 4 and 14 through 16, Ramsey does not show resistive heating elements. At best Ramsey shows electrodes, which are distinct from resistive heating elements. Thus, claims 4 and 14 through 16 are novel. These claims are also non-obvious since no one of ordinary skill would be motivated to place resistive heating elements onto the Ramsey device. They would not work to provide electrical stimulus to the heart, and Ramsey's goal of avoiding burns to the esophagus would be thwarted.

Claims 17 through 22 include limitations to the power source, requiring it to be operable to provide sufficient energy to the heating elements to thermally damage the tissue near the valve. This is directly contrary to the teaching of Ramsey, which, if it

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includes heating elements per the Examiner's assertion, does not provide a power source suitable for shrinking tissue, and takes steps to interfere with any incidental heating that might occur (without conceding that heating would occur in a trans-esophageal pacing catheter). Thus, Ramsey explicitly teaches away from the invention defined by the additional claims. Accordingly, claims 17 through 22 are both non-obvious, for the reasons stated above, and novel, since claims 17 through 22 are structurally different than Ramsey.

Conclusion

This response has addressed all of the Examiner's grounds for rejection. The rejections based on prior art have been traversed. Reconsideration of the rejections and allowance of the claims is requested.

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